A two-part parallel group study to assess the safety, tolerability and pharmacokinetic (PK) profile of multiple oral doses of RDN-929 in healthy older adults and subjects with early symptomatic Alzheimer*s Disease

Published: 30-04-2019
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primaryTo assess the safety and tolerability of multiple, once-daily oral doses of RDN-929 over 28 days in healthy older adult subjects and early symptomatic AD subjects.secondaryTo assess the plasma and CSF pharmacokinetics (PK) of RDN-929 in...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48424

Source
ToetsingOnline

Brief title
RDN-929-103 (CS0317)

Condition

- Other condition

Synonym
Alzheimer's Disease, neurodegenerative diseases

Health condition

Alzheimer's Disease

Research involving
Human

Sponsors and support

Primary sponsor: Rodin Therapeutics, Inc.
Source(s) of monetary or material Support: Rodin Therapeutics;Inc.

Intervention

Keyword: Pharmacokinetics, RDN-929, Safety, Tolerability

Outcome measures

Primary outcome

Primary Endpoints:

Safety parameters include adverse events (AEs), serious adverse events (SAEs),

physical and neurological examination, clinical laboratory values, vital signs,

12-lead ECG, and C-SSRS scores.

Secondary outcome

Secondary Endpoints:

Plasma PK and CSF parameters of RDN-929 such as Cmax and AUC as appropriate.

Exploratory Endpoints:

Part 1 and 2: PD parameters including selected biomarkers (within group changes

and mean group differences).

Part 1: PD parameters including PBMC post-translational modification (changes

over time and mean group differences)

Part 2: Quantitative Electroencephalography (qEEG), including resting state

power spectral density (PSD), functional connectivity and Event Related

Potential (ERP) acquired during neurocognitive tasks.

Mean change in [11C]-UCB-J binding in pre-defined brain regions from baseline

(Part 2 only) as measured by PET imaging.

Study description

Background summary

RDN-929 is not yet registered as medicine. This drug is being developed for the treatment of so-called neurodegenerative diseases. An example of a neurodegenerative disease is the Alzheimer's Disease. During this disease, the connections between the neuronal cells in the brain damage, which will eventually lead to neuronal cell death. The loss of these cells eventually causes the brain to dysfunction, leading to several mental and physical sympoms as a result. RDN-929 possibly improves the connections between these neuronal cells, so that the brain will function better. Previous research in animals showed that, after RDN-929 administration, the amount of connections between neuronal cells did indeed increase.

Study objective

primary
To assess the safety and tolerability of multiple, once-daily oral doses of RDN-929 over 28 days in healthy older adult subjects and early symptomatic AD subjects.

secondary
To assess the plasma and CSF pharmacokinetics (PK) of RDN-929 in healthy older adult subjects and early symptomatic AD subjects

Exploratory
Part 1: To explore the pharmacodynamics (PD) of RDN-929 in blood through analysis of peripheral blood mononuclear cells (PBMC) as well as synaptic and neuronal biomarkers in plasma and CSF in healthy older adult subjects.

Part 2:
To explore the pharmacodynamics (PD) of RDN-929 through analysis of synaptic and neuronal biomarkers in plasma and CSF in early symptomatic AD subjects.
To explore the change from baseline in quantitative Electroencephalography (qEEG) in early symptomatic AD subjects.
To assess the mean change from baseline in radioligand [11C]-UCB-J binding in pre-defined brain regions as measured by PET imaging in early symptomatic AD

subjects.

Part 1 and 2:
To explore the change from baseline in clinical measures of cognition in healthy older adult subjects and early symptomatic AD subjects.

Study design

Three (3) center, randomized, double-blind, parallel, 28-day, 4-arm study in healthy older adults (Part 1) and an open label, single arm, 28-day study in early symptomatic AD subjects (Part 2).

Intervention

RDN-929 and matching placebo

Study burden and risks

This study is being conducted in healthy volunteers and mild-to-moderate Alzheimer diseased volunteers. There are no anticipated benefitis or risks of the ligand [11C]-UCB-J Please see IMPD and IB for further information.

Contacts

Public
Rodin Therapeutics, Inc.

Winter Street 852
Waltham, MA 02451
US
Scientific
Rodin Therapeutics, Inc.

Winter Street 852
Waltham, MA 02451
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adult males or postmenopausal or surgically sterile females age 55 * 85 years old for Part 1 and age 50-85 years old for Part 2, inclusive, at the time of informed consent.
Body mass index (BMI) *18.0 kg/m2, <35.0 kg/m2.
Further inclusion criteria can be found in the protocol section 8.5.1.

Exclusion criteria

History or current evidence of any clinically significant cardiovascular, endocrinologic, hematologic, hepatobiliary, immunologic, metabolic, urologic, pulmonary, neurologic (except for diagnosis of AD in Part 2), renal, or other major disease, as determined by the Investigator.
Any conditions that, in the opinion of the Investigator, would make the subject unsuitable for enrollment or could interfere with the subject*s participation in or completion of the study.
Further exclusion criteria can be found in the protocol section 8.5.2

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	04-06-2019
Enrollment:	45
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	N.Ap.
Generic name:	[11C]-UCB-J

Ethics review

Approved WMO Date:	30-04-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-05-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-07-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-07-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	26-08-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-08-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-09-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-10-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-10-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-10-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-12-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-01-2020
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	22-01-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2019-000831-26-NL
CCMO	NL69548.056.19

Study results

Date completed:	29-01-2020
Results posted:	25-01-2021

Summary results
Trial ended prematurely

First publication
21-12-2020